REMARKS

1. Claims 1-5 are patentable over Sirhan (U.S. Patent No. 5,984,945).

In the Response to Argument section on page 9, the Examiner re-asserts that the claims do not state that the entire guidewire lumen extension has to be external to or parallel to the shaft. The Examiner also asserts that the prior art shows the tubular member and shaft are "connected" since one part of the tubular member is inserted into the shaft. MPEP 2111.01 states:

> III. <"PLAIN MEANING" REFERS TO THE ORDINARY AND CUSTOMARY MEAN-ING GIVEN TO THE TERM BY THOSE OF ORDINARY SKILL IN THE ART
>
> "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, *>415 F.3d 1303, 1313<, 75 USPQ2d 1321>, 1326< (Fed. Cir. 2005) (en banc). *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003)("In the absence of an express intent to impart a novel meaning to the claim terms, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art."). It is the use of the words in the context of the written description and customarily by those skilled in the relevant art that accurately reflects both the "ordinary" and the "customary" meaning of the terms in the claims. *Ferguson Beauregard/Logic Controls v. Mega Systems*, 350 F.3d 1327, 1338, 69 USPQ2d 1001, 1009 (Fed. Cir. 2003)

Emphasis added. Independent claim 1 recites a tubular member that (1) is connected to the shaft, (2) extends proximally from the guidewire port, (3) is external to but parallel with the shaft, and (4) is axially aligned with the guidewire lumen.

Appellants submit that, in the context of the written description and based on the customary use of "external" and "parallel" by those skilled in the art, the phrase "the guidewire lumen extension being external to but parallel with the shaft" would not be interpreted as a tubular member that is either parallel to but inside the shaft or external to but not parallel, as is described by Sirhan. Further, the use of "connected" in the context of the written description would not be interpreted by persons of skill in the art to include a tubular member merely inserted into a shaft, as asserted by the Examiner. The Examiner's interpretation of the claim is

not consistent with the use of the words in the context of the written description and the customary use of the words by those skilled in the art. The Examiner's interpretation of the claims is contradictory to MPEP 2111.01 and is thus in error.

Regarding claims 3 and 4, the Examiner has merely repeated the previous rejections and has not provided any comments in response to Appellants' arguments set forth on pages 2-3 of the Reply Brief filed January 14, 2005.

Regarding claim 5, the Examiner asserts that the guidewire lumen extension is smaller than the guide wire lumen and has walls which would create a restriction flow since the fluid or element has to be contained within the guide wire lumen extension.

The Examiner appears to be considering the specific elements recited in claim 5 to be inherent in Sirhan. Appellants submit that there is no basis for such an interpretation. MPEP 2112 IV. states:

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is **necessarily present** in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)...
>
> "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

(Emphasis added). Appellants submit that the claimed element, in particular the feature of a proximal portion of the guidewire lumen extension being sized to restrict flow about the guidewire disposed therein, is not necessarily present in Sirhan. The Examiner points to Figure 15 of Sirhan for support. Appellants submit that Figure 15 does not show a guidewire lumen extension that is necessarily sized to restrict flow about a guidewire. To the contrary, the

marked-up copy of Figure 15 of Sirhan reproduced on page 5 of the Examiner's Answer appears to show space around the guidewire. There is no teaching or suggestion in Sirhan that flow is restricted about the guidewire in Figure 15. It appears the Examiner is asserting that the structure of Sirhan could be modified to achieve the claimed structure, which is not a proper basis for anticipation.

Sirhan thus does not teach each and every limitation of the instant claims, as is required for anticipation under 35 U.S.C. §102. Withdrawal of the rejection is respectfully requested.

2. Claims 1-5, and 7 are patentable over Crittenden et al. (U.S. Patent No. 4,988,356).

In the Response to Arguments section on page 10, the Examiner asserts that the slit 28 of Crittenden forms a discrete opening for the guidewire lumen extension 48 to enter the guidewire lumen, and that this opening is a guidewire port. Appellants respectfully disagree. As discussed above, MPEP 2111.01 states:

> It is the use of the words in the context of the written description and customarily by those skilled in the relevant art that accurately reflects both the "ordinary" and the "customary" meaning of the terms in the claims. *Ferguson Beauregard/Logic Controls v. Mega Systems*, 350 F.3d 1327, 1338, 69 USPQ2d 1001, 1009 (Fed. Cir. 2003)

Appellants submit that the Examiner's interpretation of the slit 28 in the catheter 10 of Crittenden et al. would not be interpreted by one of ordinary skill in the art as the claimed guidewire port. The use of "port" in the context of the written description is as follows:

> Single operator exchange balloon catheter 10 includes an elongate shaft 12 having a distal guidewire lumen 13 as best seen in Figure 2A. The guidewire lumen 13 extends between a proximal guidewire port 14 and a distal guidewire port 16. The proximal guidewire port 14 is disposed distal of the proximal end of the elongate shaft 12 and proximal of the distal end of the elongate shaft 12. Distal guidewire port 16 is disposed at or near the distal end of the elongate shaft 12.

See page 9, lines 8-13. In particular, the proximal guidewire port 14 is described as "disposed distal of the proximal end of the elongate shaft 12 and proximal of the distal end of the elongate shaft 12. Crittenden et al. disclose, "[t]he catheter body is slit longitudinally along the guidewire lumen. The slit enables the guidewire to extend transversely into or out of the lumen through the

slit, and at any location along the length of the slit." Emphasis added; see column 2, lines 28-32. Appellants submit that the "slit" of Crittenden et al. does not have the identical structure as the "port" recited in the claims.

Further, the term "port" as is customarily used by those skilled in the art is not the structure of the slit of Crittenden et al. The use of the term "port" in the claims and in the context of the written description is consistent with its customary use by those skilled in the art, as indicating a discrete opening on a catheter. Appellants submit that those skilled in the art would not consider the slit catheter of Crittenden et al. to have the identical structure as that recited in the claims. MPEP 2131 states:

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). ... "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Appellants submit that the slit in the catheter of Crittenden et al. cannot be seen to show the identical invention in as complete detail as is contained in the claims.

Additionally, if the Examiner is considering the claimed proximal port is inherent in the teachings of Crittenden et al., the Examiner is reminded that, as discussed above:

> "'Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)

Emphasis added. The Examiner appears to be relying on the assertion that one could open the slit 28 in the catheter 10 of Crittenden et al. at a particular point and that these circumstances would lead to the claimed device. Appellants submit that this is not a proper ground for anticipation. Crittenden et al. thus fail to teach each and every limitation of independent claim 1 and the claims dependent thereon. Withdrawal of the rejection is respectfully requested.

3. Claims 1-5 and 7-9 are patentable over Horzewski et al. (U.S. Patent No. 4,771,777).

The Examiner has repeated the arguments presented in the Examiner's Answer mailed December 2, 2004, with no further comments regarding Appellants' arguments presented in the Reply Brief mailed January 14, 2005. Appellants note that in the Remand to the Examiner mailed March 24, 2006, the Board stated, "[i]n regard to the other two anticipation references, the examiner is to respond to the arguments in the reply brief which have been made in response to the explanation of the anticipation rejections, for the first time, in the examiner's answer." The Examiner has not provided any response to Appellant's arguments presented in the previous Reply Brief. Appellants' arguments are repeated below.

The Examiner argues that the structural elements of the claims are seen in figures 1 and 4 of Horzewski et al. Independent claim 1 recites a tubular member connected to the shaft and extending proximally from the proximal guidewire port. Horzewski et al. do not teach this structure. As is clearly shown in FIG. 4, Horzewski et al. teach removable slit sheath 71 disposed at a distance from proximal guidewire port 47. The Examiner argues that this structure meets the claim limitation "extends proximally from." As stated above, MPEP § 2111.01 states that claim terms are presumed to have the ordinary and customary meanings attributed to them by those of ordinary skill in the art. Appellants submit that one of ordinary skill in the art would not interpret Horzewski et al.'s teaching of sheath 71 spaced apart from port 47, as shown in FIG. 4, as extending proximally from the port.

The Examiner next argues that the phrase "in fluid communication" encompasses a situation in which if fluid were injected into the tubular member (assumed to be reference 71 in Horzewski et al. FIG. 4), some of that fluid would flow into the guidewire lumen (assumed to be reference 46). The Examiner also argues that the tubular member is capable of transferring fluid to the guidewire lumen. Appellants submit that such interpretations are inconsistent with the teachings of Horzewski et al. and are contrary to the interpretation of one of ordinary skill in the art. The phrase "in fluid communication" has a specific meaning to one of skill in the catheter art, and that meaning does not include a situation where there is the possibility that some fluid from one tubular structure might flow into another, spaced apart, tubular structure.

Regarding claims 3 and 5, see the arguments above. Horzewski et al. do not teach, and the figures do not illustrate, any structure in sheath 71 that restricts the flow about the guidewire.

Horzewski et al. fail to teach or contemplate the limitations of the claims. Withdrawal of the rejection is respectfully requested.

For the reasons stated above, the rejections of claims 1-5 and 7-9 under 35 U.S.C. §§ 102(b) and 102(e) should be reversed.

Respectfully submitted,

PAUL M. SCOPTON

By his Attorney,

Date: 6/17/08

David M. Crompton, Reg. No. 36772
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, MN 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349